

For your clinical chemistry analyzer

APPLICATION NOTE FOR BECKMAN COULTER UniCel® DxC 800 Synchron®¹

The NGAL Test™ Reagent Kit

REF/Cat. No.	ST001RA		ST002RA	ST003RA
Product name	The NGAL Test™ Reagent Kit		The NGAL Test™ Calibrator Kit	The NGAL Test™ Control Kit
	R1	R2	150, 600, 1500, 3000, 5000 ng/mL	Low and High
	1 x 35 mL	1 x 7 mL	5 x 1 mL	3 x 1 mL x 2 levels

Number of determinations: 1 mL of immunoparticle suspension **R2** provides 20 cuvette readings with the provided settings in this application. The dead volume of the analyzer and reagent container should be added when calculating the required amount of reagent.

INTENDED USE

The presented application note is intended for the quantitative determination of NGAL on Beckman Coulter UniCel® DxC 800 Synchron® analyzer in **human urine samples only. Do not use plasma samples.**

To use BioPorto's The NGAL Test™ on the UniCel® DxC 800 Synchron® chemistry analyzer the reagents must be transferred into a new container. The appropriate containers are called Beckman Coulter UDR cartridge and can be ordered from your local Beckman Coulter representative. Please make sure to acquire the following two items:

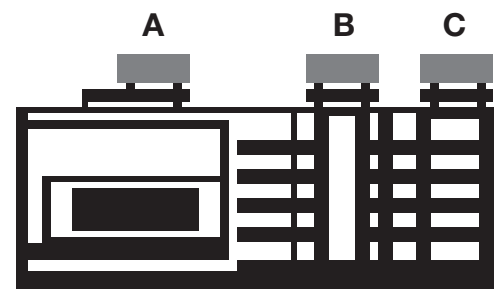
Item	Cat. No.	Product name	
Reagent container	442835	User-Defined Reagent (UDR) cartridge	Order from Beckman Coulter
Evaporation control caps for UDR cartridge	A65595	Environmental Caps	Order from Beckman Coulter



Please read the UniCel® DxC Synchron® Clinical Systems Instruction For Use before transferring the reagents.

FILLING THE BECKMAN COULTER UDR CARTRIDGE:

- Turn the UDR cartridge towards you as shown at the right (compartment A to the left and compartment C to the right).
- Unscrew the hard plastic caps on all the compartments and discard them.
- Transfer the content of The NGAL Test™ Reaction buffer **R1** into **Compartment A** on the left side and close it with the soft evaporation control cap for the UDR cartridge.
- Transfer the content of The NGAL Test™ immunoparticles suspension **R2** into **Compartment B** - the middle compartment and close it with the soft evaporation control cap for the UDR cartridge.
- Leave the Compartment C on the right side of UDR cartridge empty.



NOTE

Before loading the UDR cartridge onto the instrument, it has to be defined for a User-Defined Reagent feature.

Optional Test/Kit optimization: The Beckman Coulter DxC UDR cartridge can hold 2 full The NGAL Test™ Reagent Kits (ST001RA). Thereby the test per kit ratio can be improved from 113 per kit (when 1 kit is applied) to 247 when two kits are filled into the cartridge. Do not mix the reagents with different lot numbers.

The **NGAL** Test™

For your clinical chemistry analyzer

PRECAUTIONS

Do not pipette by mouth.
Do not shake the reagents.
Use only clean containers if transferring reagents.
Do not pour reagents back into their original containers once transferred.
Do not use reagents after the expiry date on the labels.

Do not switch caps on reagent containers as it may cause contamination or mix-up.
Reagents with different lot numbers should not be mixed.
All solutions supplied should be handled carefully and disposed of in accordance with national and local regulations.
Use calibrated pipettes to prepare the 50 ng/mL calibrator.



Regulatory status:
For Research Use Only. Not for use in diagnostic procedures.

CALIBRATION

The NGAL Test™ Calibrator Kit (REF ST002RA) should be used in the following way:

Calibration point	Kit calibrator	Level
1	Use saline as blank*	0 ng/ml
2	Calibrator 1 (150 ng/mL)**	50 ng/mL
3	Calibrator 1 (150 ng/mL)	150 ng/mL
4	Calibrator 2 (600 ng/mL)	600 ng/mL
5	Calibrator 3 (1500 ng/mL)	1500 ng/mL
6	Calibrator 4 (3000 ng/mL)	3000 ng/mL

* Saline is not included in the kit
** Special hand-dilution, 50 µL Calibrator 1 (150 ng/mL) + 100 µL Saline (dilution 1/3)

NB: ST002RA Calibrator 5 (5000 ng/mL) is not used for calibration on Beckman Coulter UniCel® DxC 800 Synchron®.

SAMPLE MATERIAL

NGAL concentrations can be determined only in human urine samples on the UniCel® DxC 800 Synchron® chemistry analyzer.

CALIBRATION STABILITY

The Beckman Coulter UniCel DxC Synchron Systems require recalibration every 2 weeks, when reagent lots change or quality control results fall outside the range as established by the individual laboratory.

TROUBLE SHOOTING

If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact instrument supplier or reagent supplier.

1. UniCel® and Synchron® are the registered trademarks of Beckman Coulter Inc., Brea, USA



NUMBER [*] CHEM [NGAL]

Chemistry Parameters		Page 1 of 3
Reaction Type	[Endpoint 2]	
Units	[12.ng/mL]	
Precision	[X.X]	
Reaction Direction	[Positive]	
Math Model	[1]	
Primary Wavelength	[520]	
Secondary Wavelength	[700]	
Calculation Factor	[1.000]	
No. of Calibrators	[6]	
Setpoints	1 [0.0]	4 [600.0]
	2 [50.0]	5 [1500.0]
	3 [150.0]	6 [3000.0]
Cal Time Limit	[336] hours	
Cal Save	[√]	

Processing Parameters			Page 2 of 3
First Inject	Component	[A]	
	Dispense Volume	[150] µL	
Second Inject	Component	[None]	
	Dispense Volume	[]	
	Inject Time	[] sec	
Third Inject	Component	[B]	
	Dispense Volume	[50] µL	
	Inject Time	[60] sec	
Sample Volume**	[6] µL		
ORDAC Volume	[3] µL		
Blank	Start Read	[70] sec	
	End Read	[100] sec	
Initial (DxC only)	Start Read	[9] sec	
	End Read	[24] sec	
Reaction 1	Start Read	[260] sec	
	End Read	[300] sec	
Reaction 2	Start Read	[] sec	
	End Read	[] sec	

Error Detection Limits			Page 3 of 3
Blank	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 1	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 2	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Substrate Depletion	Initial Rate	[99.999]	
	Delta ABS	[2.200]	
Multipoint Span	1-2 [0.001]	4-5 [0.001]	
	2-3 [0.001]	5-6 [0.001]	
	3-4 [0.001]	6-1 [0.001]	
Usable Result Range	Low Limit	[0.000]	
	High Limit	[99999.999]	
ORDAC	Low Limit	[0.000]	
	High Limit	[3000.0]	

* User Defined

** Only urine

CALIBRATION

Setpoint 1 =	Saline
Setpoint 2 =	50 ng/mL 50 µL Calibrator 1 (150 ng/mL) + 100 µL Saline (=dilution 1/3)
Setpoint 3 =	150 ng/mL Calibrator 1 (150 ng/mL)
Setpoint 4 =	600 ng/mL Calibrator 2 (600 ng/mL)
Setpoint 5 =	1500 ng/mL Calibrator 3 (1500 ng/mL)
Setpoint 6 =	3000 ng/mL Calibrator 4 (3000 ng/mL)

NB: Calibrator 5 (5000 ng/mL) is not used for DxC Calibration